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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/031,702	01/23/2002	Frank Zocher	50521	8285
26474 7	10/01/2003		EXAMINER	
KEIL & WEINKAUF			PATTERSON, CHARLES L JR	
1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			ART UNIT	PAPER NUMBER
			1652	
			DATE MAILED: 10/01/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summary	10/031,702	ZOCHER ET AL.				
Office Action Summary	Examiner	Art Unit				
TI . BEAU INC. DATE - S.M	Charles L. Patterson, Jr.	1652				
The MAILING DATE of this communication app ars on the cover she t with the cerrespondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	66(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	ely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 24 May 2002.						
2a) ☐ This action is FINAL . 2b) ☑ Thi	s action is non-final.	·				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims AND Claim(c) 1.15 is/ore pending in the application						
) Claim(s) 1-15 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-15</u> is/are rejected.						
7) ☐ Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>23 January 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☑ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)	- p	with VI IIII				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) Patent Application (PTO-152)				

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Use claims are not allowed in U.S. Patent practice. The claims must be drawn to particular processes of methods with definite steps.

Claims 1, 3-7 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in incorrect in the recitation of "Streptomyces", which should be "Streptomyces".

Claim 3 is incorrect in the recitation of "Streptomyces", "S. griseus", "S. thermovulgaris", "S. antibioticus", "S. arenae", "S. fradiae", "Streptomyces griseus", "Streptomyces thermovulgaris", "Streptomyces antibioticus", "Streptomyces arenae" and "Streptomyces fradiae", which should be "Streptomyces", "S. griseus", "S. thermovulgaris", "S. antibioticus", "S. arenae", "S. fradiae", "Streptomyces griseus", "Streptomyces thermovulgaris", "Streptomyces antibioticus", "Streptomyces fradiae".

Claim 3 is also indefinite and confusing in the recitation of "in particular" and "preferably". It is not known whether these recitation are meant to be limiting on the claim or only illustrative.

Claim 4 is incorrect in the recitation of "Streptomyces antibioticus", which should be "Streptomyces antibioticus".

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Claim 5 is incorrect in the recitation of "Streptomyces", which should be "Streptomyces". The claim is also indefinite and confusing in the recitation of "preferably in line 6.

Claim 6 is indefinite in the recitation of "which mixture is selected from...and indene oxides". The recitation should either be a Markush group that states "which mixture is selected from the group consisting of...and indene oxides" or else the recitation should be "which mixtures are...or indene oxides".

Claim 7 is indefinite in the recitation of "b) carrying out a color reaction with unreacted epoxide". It is not clear whether the "epoxide" or step "a)" is intended or some unrelated "epoxide". The claim is also indefinite in the recitation of "c)...decrease in pigment concentration". It is not clear whether this is meant to be related to somehow to "a color reaction" in step "b)" or to some unrelated "pigment concentration".

Claim 10 is indefinite in the recitation of "A process as claimed in claim 9". Claim 9 is drawn to a method and therefore the instant recitation does not have antecedent basis.

Claims 10 and 13-15 are incorrect in the recitation of "Streptomyces", which should be "Streptomyces".

Claims 11 and 12 are indefinite in the recitation of "and/or".

Claim 15 is incorrect in the recitation of "is produce" on line 2, which should apparently be "is produced" The claim is also indefinite and confusing in the recitation of "if appropriate" in line 5 and 7-8. It is not clear whether this is meant as a limitation on the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear,

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concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claim requires the presence of a particular strain of organism, namely *Streptomyces antibioticus* Tu4. It is not clear that all of the requirements of 37 CFR 1.801-1.809 as to deposit conditions and availability upon issuance of a U.S. patent have been met.

Claims 1-3, 5-6 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Streptomyces antibioticus, S. fradiae, S. arenae, S. griseus and S. thermovulgaris, does not reasonably provide enablement for other strains of the genus Streptomyces. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches that Streptomyces antibioticus, S. fradiae and S. arenae have epoxide hydrolases in Examples 3-7 and it is stated in the specification that S. griseus and S. thermovulgaris also have the enzyme. There is no assurance that any and all strains of Streptomyces have this enzyme and absent a convincing argument to the contrary, the claims should be limited to these four species.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Zocher, et al. (AJ). The instant reference teaches the instant claims. Although this is apparently the work of all of the applicants, there is a additional name listed as author and therefore it is by a different inventive entity. The date of the reference is 2000 and since no month of day is given, it is maintained that it is prior to 7/26/00. Applicants may not use the German priority date because a certified copy of the application is not of record.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Lutz-Wahl (AG). The reference teaches the strain of the instant claim in Table 1.

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Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Rink, et al. (AD), Zocher, et al. (AH) or Nells, et al. (U).

Rink, et al. teach a method of analyzing for epoxide hydrolase activity by using a substrate and 4-nitrobenzylpyridine as a color reagent. Zocher, et al. also teach a colorometric assay for screening for epoxide hydrolase activity. It would have been obvious to one of ordinary skill in the art to use the method of these two references to detect epoxide hydrolase activity in *Streptomyces*, absent unexpected results.

Nells, et al. teach in at least Figure 1 that 4-(p-nitrobenyl)pyridine (NBP) will react with epoxides. Since epoxide hydrolases are known to hydrolyze epoxides, it would have been obvious to one of ordinary skill in the art to use NBP as a reagent in the assay of epoxide hydrolases, absent unexpected results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr. Primary Examiner

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Patterson September 30, 2003